Exactech®

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K031847
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JAN 2 2 2004

# Tecres Spacer-G

## Summary of Safety and Effectiveness
## Traditional 510(k)

Applicant/ Consultant: **Exactech® Inc.**
**2320 N.W. 66th Court**
**Gainesville, Florida 32653**

**Phone:** **(352) - 377 - 1140**
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***Contact:*** **Gary J. Miller, PH.D.**
**Exec. V.P. of R&D**

Manufacturer/Submitter: **Tecres S.p.A**
**FDA Owner/Operator ID# 9033624**

Date: **October 24, 2003**

# Tecres Spacer-G

## Summary of Safety and Effectiveness
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**Classifications / Proprietary Names:**

| | |
|---|---|
| Classification Name: | Hip joint, femoral (hemi-hip), metallic, cemented or uncemented |
| Product Code: | KWY |
| C.F.R. Section: | 888.3390 |
| Device Class: | II |
| Classification Panel: | Orthopedic |
| Trade / Proprietary Model Names: | Spacer-G<br>Temporary Hip Prosthesis |

**Legally Marketed Device for Substantial Equivalence Comparison:**

The Spacer-G device is substantially equivalent to the "Osteo Austin Moore Endoprosthesis" (Osteonics Corporation). The "Osteo" device was cleared for marketing through premarket submission #K974807.

| Model | Manufacturer | 510(k) Number |
|---|---|---|
| Osteo Austin Moore | Osteonics | #K974807 |

**Device Description:**
The Spacer-G is a "hemi-hip" style device. The one-piece design incorporates a load bearing endoskeleton of AISI 316L stainless steel and an outer coating of fully formed gentamicin/polymethylmethacrylate (PMMA) bone cement. The implants are supplied sterile to an assurance level (SAL) of $10^{-6}$.

Spacer-G is indicated for temporary use (maximum 180 days) as an adjunct to total hip replacement (THR) in patients undergoing a two-stage procedure due to a septic process.

The device is inserted into the femoral medullary canal and acetabular cavity following removal of the existing femoral and acetabular implants and debridement. The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

Spacer-G is not intended for use for more than 180 days, at which time it must be explanted and a permanent device implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion etc.).

# Tecres Spacer-G

## Summary of Safety and Effectiveness
## Traditional 510(k)

### CONTRAINDICATIONS

Use of Spacer-G is contraindicated in the following situations:

- The patient's condition is such that a two-stage arthroplasty procedure is contraindicated due to decreased immune response or other relevant systemic clinical conditions.
- Lack of adequate bone structure precludes adequate support of the prosthesis in the proximal femur or acetabular region.
- The procedure is unjustified due to deficiencies in the patient's muscular, nervous or vascular systems.
- Poor bone quality (as in osteoporosis) could cause the prosthesis to migrate or to fracture host bone.
- Infection of the THR cannot be confirmed.
- The infected THR devices cannot be removed.
- The infecting pathogens are resistant to gentamicin.
- The patient is sensitive (allergic) to gentamicin, aminoglycosides or PMMA bone cement.
- A systemic or secondary remote infection is suspected or confirmed.
- The patient does not have a THR and the infection is secondary to trauma, septic arthritis or other surgical procedures.
- The patient does not have sufficient bone stock to allow insertion and fixation of the prosthesis
- The patient has neuromuscular disorders that do not allow control of the hip joint.
- The patient's weight, age or activity level would cause the surgeon to expect early failure of the system.

### PERFORMANCE DATA

Performance testing was conducted to verify that the implant performance would be adequate for anticipated *in vivo* load applications under the temporary conditions of use. The fatigue strength, static strength, wear characteristics and antibiotic release rate were evaluated and found to support the safety and effectiveness of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2004

Gary J. Miller, Ph.D.
Executive Vice President
Research and Development
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K031841
Trade/Device Name: Tecres Spacer-G
Regulation Number: 21 CFR 888.3360, 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis, Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWL, KWY
Dated: October 24, 2003
Received: October 27, 2003

Dear Dr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Tecres Spacer-G**
**Indications for Use**

**510(k) Number:** K031841

**Device Name:** **Tecres Spacer-G**

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- The patient's weight, age or activity level would cause the surgeon to expect early failure of the system.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 21 CFR 801.109 or Over the Counter Use _____



Mark N Milleson
Neurological Devices
K031841